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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/361,652	07/27/1999	CHARLES S. ZUKER	2307E-88610	5785

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER

BRANNOCK, MICHAEL T

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 06/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/361,652	Applicant(s) ZUKER ET AL.	
	Examiner Michael Brannock	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-6,8,34,35 and 61-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-6,8,34,35 and 61-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application: Claims and Amendments

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/2/04 has been entered.

Applicant is notified that the amendments put forth on 6/2/04, have been entered in full.

Response to Amendment

Applicant is notified that any outstanding objection or rejection that is not expressly maintained in this Office action has been withdrawn in view of Applicant's amendments.

New Rejections:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-6, 8, 34, 35, and 61-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The claims have been amended to require that the claimed polynucleotide encode a receptor that binds to a glutamate ligand. It is unclear what Applicant intends the phrase “glutamate ligand” to encompass and the phrase does not appear in the specification. It is unclear if the phrase is synonymous with “and binds glutamate” or if the phrase encompasses other substances beside glutamate. A Medline search of the phrase reveals that it is not used often in the art. The phrase “glutamate ligand”, used as a noun, is sometimes used in the art to mean ligands other than glutamate that bind glutamate receptors, e.g. NMDA, but more often the phrase refers to part of the active center of an enzyme and refers to a glutamate residue that is part of the primary structure of the enzyme.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-6, 8, 34, 35, and 61-63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As set forth above, the claims have been amended to require that the claimed polynucleotide encode a receptor that binds a glutamate ligand. There is no such mention of this phrase in the specification. Applicant points to the page 8 of the specification for support, however the phrase is not used there.

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Maintained Rejections:

Claims 1, 4-6, 8, 34, 35, and 61-63 stand rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility, as set forth item 9 of Paper 12 (1/3/01).

Applicant argues, essentially, that Nelson et al. demonstrate that the instant GPCR-B3 is one half of a functional amino acid taste receptor, thus supporting Applicant's assertion GPCR-B3 has a defined role in taste signal transduction. This argument has been fully considered but not deemed persuasive. The definition of the role of GPCR-B3 in taste signal transduction is provided in the Nelson et al. paper but not in the instant specification.

Applicant argues that Nelson provide evidence that GPCR-B3 could be used to assay for modulators of taste perception as asserted in the specification e.g. at page 11. This argument has been fully considered but not deemed persuasive. The skilled artisan would appreciate that Nelson et al. show that GPCR-B3 in combination with T1R1 could be used to assay for modulators of taste perception; however the instant specification does not point to such a combination.

Claims 1, 4-6, 34, 35, and 61-63 also stand rejected under 35 U.S.C. § 112 first paragraph, as set forth in item 10 of Paper 12. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation, as set forth previously.

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Applicants' arguments regarding the 35 U.S.C. § 112 rejection as the corollary of the 35 U.S.C. § 101 rejection have been addressed above.

Additionally, the specification has failed to show how to get a polypeptide of SEQ ID NO: 1, 2, or 3 to bind glutamate, or any other ligand, or to induce GPCR activity. As set forth above Nelson et al. show that GPCR-B3 in combination with T1R1 could be used to assay for modulators of taste perception; however the instant specification does not point to such a combination. There is no record of the instant polypeptides either binding to glutamate or having any functional GPCR activity. As admitted by Applicant, the functional polypeptide referred to in the specification is a chimeric polypeptide wherein the extracellular domain of the murine MGluR1 receptor was required to make a functional GPCR and to bind glutamate.

Claims 1, 6, , 34, 35 61-63 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as set forth in item 11 of Paper 12.

Applicant argues that the recitation of binding of a glutamate ligand is an actual particular function, thus adequately providing a functional limitation. This argument has been fully considered but not deemed persuasive. First, as discussed above, it is unclear what is to be encompassed by the phrase "a glutamate ligand", so it is impossible to determine what Applicant was in possession of. It would be agreed, however, that "binds glutamate" would be a definitive functional phrase. But this is only part of the issue. The skilled artisan appreciates that simply writing down or verbalizing that an unknown protein should have a definite function in no way

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places one in possession of such a protein. Nor does the writing down of hybridization conditions put one in possession of a polynucleotide encoding such a protein.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, Ph.D., can be reached at (571) 272-0887.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

MB

ELIZABETH KEMMERER
PRIMARY EXAMINER



June 23, 2004